A Prospective Cohort Study of Continency Management Using a Smartphone App Application in Patients with Substance Use Disorder

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Title:

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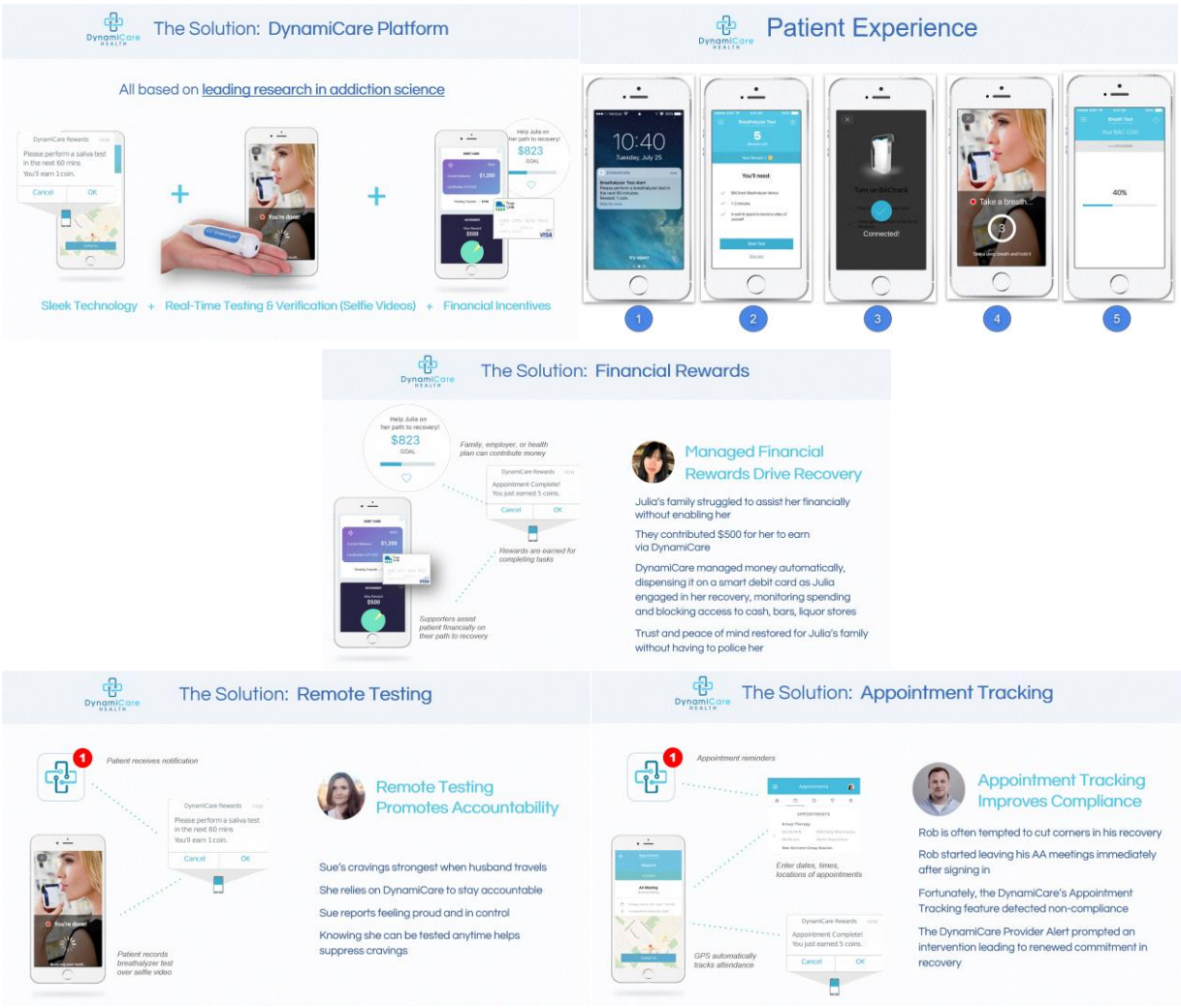
A. Type of Research

To test the acceptance and efficacy of a smartphone app (DynamiCare Rewards™) for patients with substance use disorder (SUD) who are in active treatment and recovery at BrightView centers. Patients will perform self-tracking of their recovery behavior (e.g., counseling attendance, abstinence from drugs and alcohol) and the application will support their motivation to maintain their desired health behaviors through the implementation of contingency management (CM) through the DynamiCare smartphone app. This device poses non-significant risk to participants and is exempt from IDE regulations [21 CFR 812.2(c)].

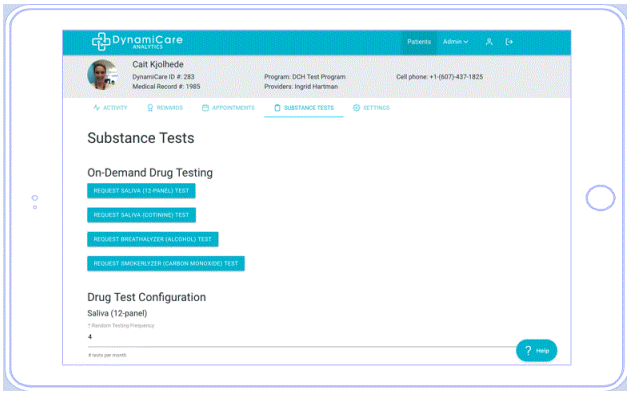
B. Background/Purpose of the Study

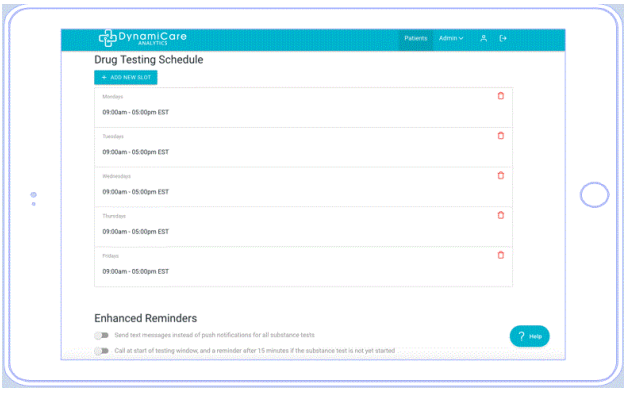
Opioid dependence (OD) is a chronic relapsing disorder [1]. Like in other chronic conditions, its treatment should be open ended and should comprise long-term care strategies and regular monitoring; medication should be accessible, with dosing and duration based on scientific evidence [2]. Based on a multitude of studies in various settings, medication assisted treatment (MAT) has been recognized as the treatment of choice for opioid dependence. The typical perspective on treatment retention, one of the pivotal outcomes used for evaluation of MAT, contributes to this phenomenon by obscuring the chronic nature of opioid dependence [3-6]. When MAT is provided, long-term treatment is restricted by abstinence from substance use as precondition to enroll or stay in treatment [7]. Contingency Management (CM) is shown as a highly effective, evidence-based methodology for improving substance use disorder (SUD) outcomes. It does so by activating the brain's reward and inhibitory systems through both positive and negative reinforcement using immediate, concrete incentives in a progressive reinforcement schedule. CM involves setting frequent (>1/week), objective goals (usually abstinence or participation in treatment), which patients can achieve to earn tangible rewards (such as cash or vouchers) [8-10]. Therefore, an automated version of CM for patient self-tracking (DynamiCare Rewards™) which does not require substantial staff effort, could be beneficial to improve patient outcomes. The DynamiCare smart phone app (iOS/Android) uses CM to incentivize patients to attend scheduled appointments and to submit negative alcohol and drug tests as they are rewarded for these behaviors. The DynamiCare smart phone app will be used to see if treatment retention can be increased when this app is added to treatment as usual, as well as whether the percentage of scheduled appointments can be increased by using the app. In addition, we want to see if using the DynamiCare app can reduce substance use. The intentions of this project are to assess whether use of the



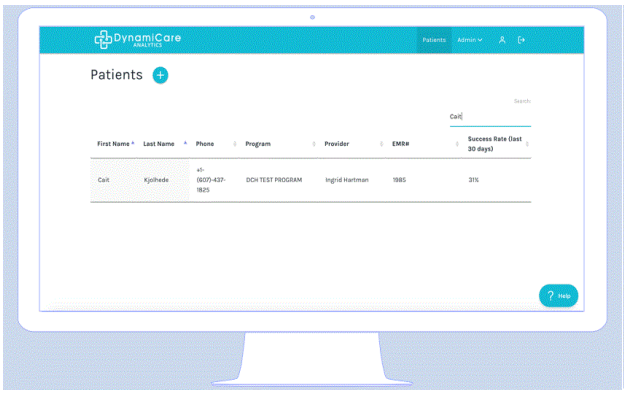
smartphone app as an add-on to treatment as usual can increase treatment retention, increase the percentage of appointments that are kept, and whether substance use can be reduced (Please see snapshots).

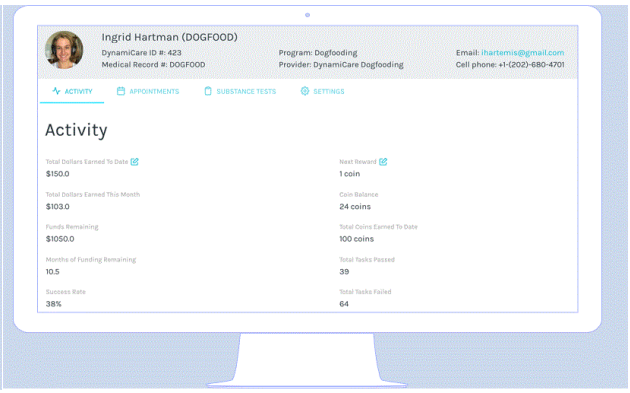
In this study, we aim to: 1) promote an overlooked yet effective evidence-based methodology which consistently tracks the patients and improves patient medical outcomes; 2) overcome known barriers by using an automated solution (the DynamiCare platform; please see snapshots) to benefit patients, families, providers, and payers, and 3) validate the system's acceptability and initial efficacy in a pilot study that will inform Phase II efficacy and integration testing. We believe we can





build a rapidly scalable, sustainable process that makes the field of addiction treatment more effective, accountable, and accessible using the DynamiCare Rewards™.





C. Objectives of the Study

The objectives of study are:

i. Reduction in drug use – As measured by urine toxicology results. Percentage of patients testing consistent only for prescribed substances in random clinical urine tests.

ii. Retention –Percent of patients who are still active in the DynamiCare app and/or attending treatment sessions after 1, 2, 3, 4 months. Post-intervention retention at BrightView at 6 months will also be measured.

iii. Attendance – As measured by % of attendance of medical and clinical appointments.

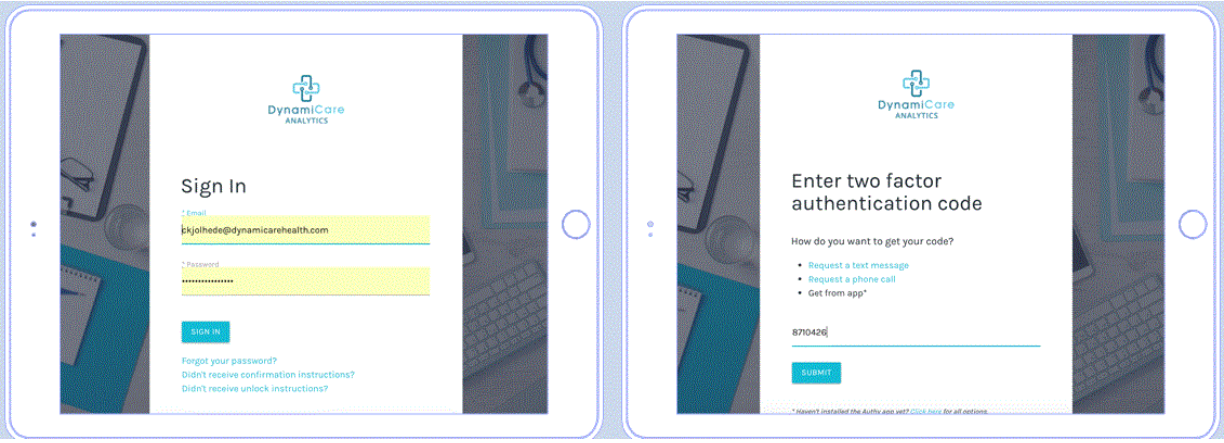
D. Study Design and Prevention of Risks

Prospective cohort study- This study will focus on controlled trial of a 4 months-long using DynamiCare app to track and reward 100 patients with drug addiction who are enrolled at Brightview programs. Comparative outcomes will be measured against 100 patients at a different but similar

BrightView treatment site. A subject participating in the study may experience potential medical benefits, i.e., increased awareness and focus on achieving desired health goals, i.e., maintenance of abstinence from drug use. Participants in the pilot study will be enrolled at BrightView outpatient SUD programs who are: 1) >18 years old; 2) SUD as the primary substance use problem; 3) have and use an Android or iOS smartphone with acceptable capability; 4) are willing to participate in home testing and use of the smartphone, 5) speak and read the English language adequately to understand smartphone commands and responses and 6) are willing to be randomly assigned to receive treatment with or without the smartphone app as an added feature.

The study design will prevent or minimize potential risks or discomforts to the greatest extent possible *via* having patients use a passcode on their smartphones, use of a random code number for patient record identification rather than patient names, data encryption for all electronic transmissions, destruction of substance testing video selfies in the immediate timeframe following test validation, and use of HIPAA-compliant data storage servers (please see the snapshot).

After completing the Informed Consent process, a baseline assessment will then be conducted with consented participants prior to any other study procedures and participants will provide baseline demographic data and information on their recent substance use and severity using the self-administered Brief Addiction Monitor. In addition, a urine sample will be collected at baseline and each study visit as indicated by the ASAM guidelines to be tested for substances in routine clinical urine tests. Breathalyzers



may be used when indicated for patients with Alcohol Use Disorder or when there is concern for problematic alcohol use. Study procedures related to the DynamiCare Rewards intervention are conducted *via* smartphone.

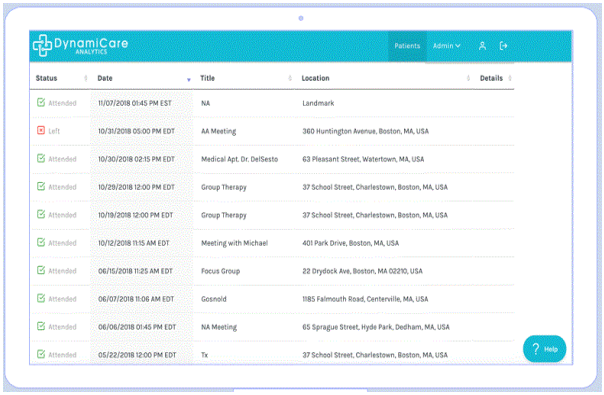
E. Procedures for the Study

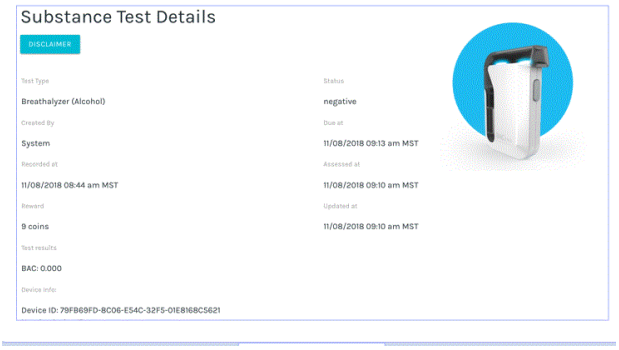
If the patient is interested, information about study procedures and requirements will be provided for review as well as a video describing the DynamiCare Rewards program. If the patient remains interested and If eligibility criteria are met, research member will meet with the patient, review the eligibility criteria, answer any questions about the study, and obtain written Informed Consent. A baseline assessment will then be conducted with consented participants prior to any other study procedures.

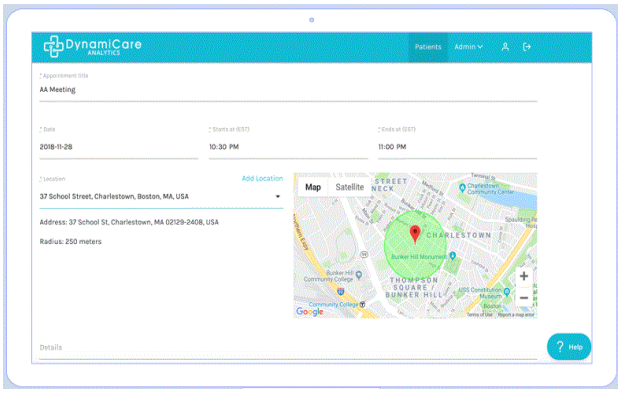
After completing the Informed Consent process, participants will provide baseline demographic data and information on their recent substance use and severity. In addition, a urine sample will be

collected at baseline and each study visit as indicated by the ASAM guidelines. Breathalyzers may be used when indicated for patients with Alcohol Use Disorder or when there is concern for problematic alcohol use.

Study procedures related to the DynamiCare Rewards intervention are conducted via smartphone and there are no visits related to the study intervention. Research visits including collection of a urine sample and medical exams. Participants assigned to the DynamiCare Rewards group will receive: 1) the app on their smartphone, 2) drug testing devices when indicated (pocket-sized breathalyzer), and a reloadable debit card for receiving the financial incentives (the PEX debit card). The app will periodically prompt the user to deliver a urine drug test or conduct a breathalyzer. The breathalyzers (BACTrack Mobile Pro) submit BAC results directly to the smartphone app via Bluetooth. When taking these tests, patients take selfie videos of themselves and these videos are loaded to DynamiCare's Analytic website where they are viewed by trained personnel to ensure that they are valid. Videos are kept for 7 days and then destroyed. GPS tracking also ensures that patients have attended their scheduled appointments. GPS is not used at any other times. All information is uploaded on the DynamiCare Analytic website where providers can see the status of patients. Information includes whether appointments have been attended, the status of all alcohol and drug testing, and incentives earned. (please see snapshots).







Negative tests result in points which the patient can immediately transfer from a reserve account (where the patient's incentive funds are inaccessible), to the spendable PEX debit card. The amount of funds are available on a progressive variable reward schedule. The app provides reminders to patients for all therapy and drug/alcohol testing appointments. It also informs providers if appointments have been kept, and whether breathalyzer and oral saliva testing has been completed as well as the results of these rests. Both providers and patients can schedule appointments. Patients do this via the app; providers via the DynamiCare Analytic website.

The PEX card provides a convenient way to monitor and protect the patient from risky spending. The card will block cash withdrawals, and spending at identified liquor stores and bars. All substance testing devices and the debit card are existing, commercially available, valid and reliable products. At all times, the participant retains the right to choose whether to use, and when to use the devices and funds.

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